Lower Esophageal Sphincter Stimulation System

Clinician Manual

(With EndoStim II LES Stimulator Model 1006)

CE **0344,1588**

Year of Authorization: 2013

EndoStim® is a registered trademark of EndoStim B.V.

Read all accompanying documentation before using the device.

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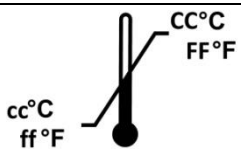
Explanation of Symbols on Labels

SYMBOL	DESCRIPTION
	Manufacturer
	Date of Manufacture
	Affixed in compliance with European directives 0344 = Notified Body Number for Directive 90/385/EEC
	Affixed in compliance with European directives 0344 = Notified Body Number for Directive 90/385/EEC 1588 = Notified Body Number for Directive 1999/5/EC
	Consult instructions for use.
	Do Not Use if Package is Damaged or Opened
	Transport Temperature Limits
	Sterilized with Ethylene Oxide
	Use By
	Do Not Reuse

SYMBOL	DESCRIPTION
	Do not resterilize
	Part Number
	Lot Number
	Serial Number
	Open Here
	Torque Wrench
	Type B Applied Part
	Caution
	Power Indicator
	Intentional Radiator
	Signal Strength Indicator
	USB Connector
	MR Conditional

SYMBOL	DESCRIPTION
	MR Unsafe

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List of Acronyms and Abbreviations

BMI	Body Mass Index
CISPR	International special committee on Radio Interference
IPG	Implantable Pulse Generator
MR	Magnetic Resonance
MRI	Magnetic Resonance Imaging
RF	Radio Frequency
T2DM	Type 2 Diabetes Mellitus
TENS	Transcutaneous Electrical Nerve Stimulation

Device Description

Contents of all Packages

Model 1011 EndoStim LES Stimulator and Lead Package

- 1 Model 1006 EndoStim II Implantable Pulse Generator
- 1 Model 1003 EndoStim Implantable Bipolar Stimulating Lead
- 1 Torque wrench (Allen-type)
- 1 Set peel-off labels for IPG
- 1 Set of peel-off labels for Lead

Model 1006 EndoStim LES Stimulator Package

- 1 Model 1006 EndoStim II Implantable Pulse Generator
- 1 Torque wrench (Allen-type)
- 1 Set peel-off labels for IPG

Model 1012 EndoStim LES Programmer System

- 1 Model 1504 EndoStim LES Programmer USB Wand
- 1 Model 1522 Tablet PC with EndoStim LES Programmer Software

Accessories

- Standard pulse generator and lead accessories – magnet, lead cap, lead extenders, torque wrench

Indications and Contraindications

Indications

The EndoStim LES Stimulation System is intended for the treatment of patients with chronic Gastroesophageal Reflux Disease (GERD) with symptom duration of 6 months or longer.

Contraindication

The EndoStim Lower Esophageal Sphincter Stimulation System is contraindicated for individuals with the following conditions or needs:

- Significant cardiac arrhythmia, or ectopy, or significant cardiovascular disease.
- Pregnant or nursing.

The following treatments are contraindicated for patients implanted with the EndoStim device:

- Medical diathermy
- Transcutaneous Electrical Nerve Stimulation (TENS) exposure in the abdominal region

Precautions

The EndoStim Lower Esophageal Sphincter Stimulation System has not been evaluated in the following populations. Patients with the following conditions should be considered prior to implant

- Large (greater than 3 cm) hiatal hernia that has not been repaired
- Severe Grade D esophagitis
- Long segment Barrett's esophagus or Barrett's esophagus with dysplasia
- Significant uncontrolled autoimmune disorder such as Scleroderma, Dematomyositis, CREST syndrome, Sjogren's Syndrome, or Sharp's Syndrome, that affects esophageal motility

- Severe obesity that in the opinion of the surgeon increases the risk of a laparoscopic implant procedure
- Type 1 diabetes mellitus
- Uncontrolled type 2 diabetes mellitus (T2DM) defined as HbA1c > 9.5 in the previous 6 months, or has T2DM for more than 10 years
- Suspected or confirmed esophageal or gastric cancer
- Esophageal or gastric varices
- Dysphagia due to severe esophageal peptic structure, excluding Schatzki's ring
- History of any advanced malignancy
- History of previous surgery such that directly involves the lower esophageal sphincter or the EndoStim electrode implant site, e.g., fundoplication or an esophageal myotomy
- Other implanted electro-medical devices
- Younger than 21 years old

Potential Adverse Effects/Events

Implantation of the System

Potential adverse effects/events associated with the implantation of the implantable pulse generator (IPG) and lead include, but are not limited to, the following: death; pulmonary embolism; partial or complete ileus; peritonitis; esophageal perforation by the electrodes; infection; inflammation; injury to organs within the abdominal cavity; intravenous site complications; pneumonia; bleeding; incisional hernia; allergic or abnormal reaction to anesthetic agents; pain; and fever.

Use of the System

Additional adverse effects that could be associated with the EndoStim System include, but are not limited to, the following: lead/electrode dislodgement; lead erosion or perforation into the esophagus or stomach; IPG migration in the subcutaneous space; IPG erosion through the skin; diaphragmatic stimulation; stimulation of abdominal muscle; irritation and/or inflammatory response to the IPG and/or the lead; allergic reaction to materials; hematoma; infection; dysphagia; odynophagia; cardiac arrhythmia; nausea; and discomfort. LES stimulation ceases when the battery in the IPG is completely discharged.

There is a potential that any system component could malfunction (e.g., software bug), become damaged (e.g., lead fracture), or the patient's incision could become infected. System component malfunction or other clinical circumstances (e.g., sepsis) may require noninvasive corrective actions or possibly even a surgical revision (repositioning, replacement, or removal) of the malfunctioning component(s).

It is recommended to shut the system down if the patient experiences severe sensation or muscle or diaphragm stimulation.

Notes:

- If necessary, use the Programmer to adjust the stimulation amplitude to eliminate any pain, discomfort, or sensation that may be related to stimulation. Reducing stimulation amplitude is the only recommended adjustment. After verifying the IPG is functioning as previously programmed, it is recommend reducing stimulation amplitude, incrementally in voltage steps of 0.5mA, until the adverse effect resolves. If such attempts are not successful, it may be necessary to use the Programmer or a magnet to shut down the system.
- A dramatic increase of the lead impedance may indicate a partial or complete lead dislodgement. Patient symptoms should be monitored and, if deteriorating, x-ray or fluoroscopy is recommended to assess the lead and electrode location.

Warnings and Precautions

Cremation and Incineration

The IPG contains a sealed chemical power cell (lithium battery). For this reason, never incinerate an IPG. Be sure that the IPG is explanted before a deceased patient is cremated. Contact your local waste management officials for other information about the environmentally safe collection and disposal of the IPG.

Dropping and Damage

Do not implant the IPG if the package is damaged or if the IPG has been dropped from a height of 30 cm or more.

Do not implant the Lead if the package is damaged or if the IPG has been dropped from a height of 30 cm or more.

Do not use the Programmer if the package is damaged or if the Programmer has been dropped from a height of 1 meter or more

Reuse

The IPG and implanted lead are intended for single use only.

Environmental Hazards

The following discussion reflects a conservative approach to the issue of patient safety in the presence of potential environmental hazards. Design features in the IPG minimize the potential for such hazards, but they cannot be ruled out completely.

Notes:

- Do not use any other electrical equipment adjacent to the EndoStim System. If the components cannot be kept separate, then monitor devices to assure normal operation.
- Portable and mobile RF (radio frequency) equipment can interfere with the normal operation of the EndoStim System. The portable and mobile RF equipment should be considered in any situation where the EndoStim System devices are not acting as expected. Other equipment may interfere with these devices, even if that equipment complies with CISPR emission limits.

As with any medical device system, all the components of the EndoStim System can be affected by magnetic, electrical, and electromagnetic signals of sufficient strength. On rare occasions, interfering signals could inhibit electrical stimulation delivery or, alternatively, trigger inappropriate delivery of electrical stimulation signals. In addition, certain sources can couple sufficient energy into the IPG to damage the circuitry of the IPG and/or LES tissue adjacent to the electrodes. The physician may wish to discuss these risks with the patient.

The susceptibility of a particular unit will also depend on the location of the IPG pocket, the nature of the interference, and the programmed operating parameters.

Because of the diversity of potential causes of electromagnetic interference, EndoStim cannot characterize and describe within this manual the effects of all potential sources of interference.

Warning: Advise patients to be cautious when in the vicinity of equipment that generates electrical or magnetic fields and to seek medical advice before entering an area posted with a warning for pacemaker patients (or other medical implantable devices).

Electrocautery

The surgical use of electrocautery can cause the IPG to become inactive and possibly lose statistical data. Electrocautery may damage the IPG and lead. Application of electrocautery close to an IPG can also cause damage to the LES tissue, possibly producing burns.

If electrocautery is required, apply it in short bursts; position the ground plate on the patient to minimize current flow through the IPG and lead. To reduce the possibility of adverse effects, program the IPG to the OFF mode. Check the IPG for proper operation immediately following the procedure. If the unit is in the DOWN mode, follow the Reset procedure.

RF Ablation

RF Ablation can cause the IPG to revert to its DOWN mode, with possible loss of statistics data. If sufficient energy is coupled into the system, the unit may be damaged. Application of RF ablation in close proximity to the electrodes of an implanted IPG can also cause a direct coupling of radio-frequency energy through the leads and electrodes to the LES tissue, possibly producing burns.

If RF ablation is necessary, position the ground plate as far from the IPG and lead as possible. Avoid direct contact with the ablation catheter and the IPG and lead. Program the IPG to the OFF mode to reduce the possibility of adverse effects. Check the IPG for proper operation immediately following the procedure. If the unit is found in the DOWN mode, follow the Reset procedure.

Medical Diathermy

Medical diathermy (short-wave thermal induction) is generally contraindicated for patients implanted with active medical devices. It is unknown how the IPG will operate if subjected to the intense fields of energy. Although damage to either the circuitry of the IPG or LES tissue is improbable, it cannot be ruled out.

If medical diathermy is required, apply it away from the immediate vicinity of the IPG and lead. Programming the IPG to the OFF mode reduces the possibility of adverse effects. Check the IPG for proper operation immediately following the procedure. If the unit is in the DOWN mode, follow the Reset procedure.

Contraindication: Patients and physicians should be advised that exposure to medical diathermy is contraindicated in patients implanted with the EndoStim System.

Defibrillation

Any implanted active medical device can be damaged by cardiac defibrillation procedures. In addition, the defibrillation current can cause damage to LES tissue adjacent to the electrodes and/or to tissue surrounding the IPG. The defibrillation current may also cause the IPG to revert to its DOWN mode, with possible loss of statistics data. If sufficient energy is coupled into the system, the unit may be damaged. If defibrillation is necessary, position the paddles as far away from the implanted system as possible; avoid placing the IPG in the defibrillation current path between the paddles.

Following defibrillation, closely monitor the performance of the IPG. If an operational abnormality is detected, consider repositioning or replacing the lead and/or reprogramming (or replacing) the IPG. If the IPG changes to the DOWN mode, follow the Reset procedure.

Therapeutic Radiation

Therapeutic equipment that produces ionizing radiation, such as linear accelerators and cobalt machines used in cancer treatment, can damage the type of circuitry used in most active implantable medical devices. Since the effect is cumulative, both dose rate and total radiation dosage determine whether, and to what extent, damage will occur. Please note that any damage to the IPG may not be immediately detected.

In addition, the electromagnetic fields generated by some therapeutic machines as part of the energy “steering” process can affect the operation of the IPG.

The effects of radiation therapy can range from temporary disturbance to permanent damage. Therefore, if such therapy is used, protect the IPG with local radiation shielding, and monitor its performance during and after treatment. If tissue near the implant site must be irradiated, it may be advisable to relocate the IPG.

Magnetic Resonance Imaging (MRI)

The EndoStim System is MR conditional and high specific conditions must be followed to ensure patient safety. This includes using 1.5-Tesla/64-MHz or 3-Tesla/128-MHz MR systems and a transmit/receive RF local coil (e.g., head coil), ONLY. Other conditions must be followed to ensure patient safety. Failure to carefully follow all labeling conditions may result in serious patient injury and/or damage to the EndoStim System.

Lithotripsy

Direct exposure of an IPG to lithotripsy shock waves can cause damage to the IPG. If the implant site is outside of the shock-wave path, no clear contraindication to the use of lithotripsy can be established.

As a precaution, programming the IPG to the OFF mode reduces the possibility of adverse effects. Check the IPG for proper operation immediately following the procedure. If the unit is found in the DOWN mode, follow the Reset procedure.

Therapeutic and Diagnostic Ultrasound

Direct exposure of an IPG to diagnostic ultrasound can cause damage to the IPG. The IPG may inadvertently concentrate the ultrasonic field and cause harm to the patient.

Therapeutic ultrasound may be used if the implant site is distant and clearly outside of the ultrasonic field. Programming the IPG to OFF mode reduces the possibility of adverse effects. Check the IPG to assure operation immediately following the procedure. If the unit is found in the DOWN mode, follow the Reset procedure.

Effects on Other Implanted Devices

The EndoStim system may affect the operation of other implanted devices, such as cardiac pacemakers, implantable cardioverter defibrillators (ICDs), other neurostimulation systems, and implantable drug infusion pumps. Physical proximity may cause sensing problems and inappropriate device responses. Clinicians involved with both devices should evaluate any potential interference problems before surgery.

Transcutaneous Electrical Nerve Stimulator

Transcutaneous Electrical Nerve Stimulator (TENS) therapy is generally contraindicated for patients who have active implantable medical devices. The high-voltage pulses delivered by TENS units to the body can interfere with the operation of the IPG.

If a TENS device must be used, place the TENS electrodes as far from the IPG and lead as possible. The TENS electrodes should also be placed as close as possible to each other to reduce current spread. The operation of the IPG should be monitored closely during TENS use. As a precaution, programming the IPG to the OFF mode reduces the possibility of adverse effects.

Contraindication: Patients and physicians should be advised that exposure to TENS in the abdominal region is contraindicated for patients implanted with the EndoStim System.

Home Appliances

Home and commercial microwave ovens in good condition, and used as intended, will not affect the IPG. Even a defective oven that exposes the IPG to direct microwave energy may not damage the unit itself. Ovens using electromagnetic induction can cause the device to go into magnet mode (disable stimulation therapy output).

Inform patients about the possibility of interference from some electric razors, electric power tools and electrical ignition systems, including those used on gasoline-powered devices. In general, patients who have an IPG may operate gasoline-powered devices if protective hoods, shrouds, and other shielding remain in place.

Antitheft Systems

Certain types of antitheft devices, such as those used at entrances/exits of retail stores, libraries and other establishments, can interfere with the IPG. Most commonly, interference may result in electrical stimulation delivery inhibition. Instruct patients to walk at a normal pace and avoid lingering when passing through the entrances and exits of these establishments.

Industrial Machinery

High voltage power lines, electric arc welders, electric smelting furnaces, and power-generating equipment can interfere with the operation of the IPG. For this reason, the intensities and modulation characteristics of the electromagnetic fields encountered by patients as a result of their occupation and lifestyle should be considered. When appropriate, give specific warnings.

Radio Transmitters

Communications equipment such as radio and TV transmitters (including amateur “ham” transmitters, microwave transmitters and CB transmitters with high-power linear amplifiers) and radar transmitters can interfere with the operation of the IPG. Discuss this with patients whose occupations may expose them to these electromagnetic fields. When appropriate, give specific warnings.

Cellular Phones

Cellular and other portable telephones can interfere with the operation of the IPG. Potential effects may result from either the radio frequency emitted by these telephones or the magnet within the phone's speaker. These effects may include inhibition or inappropriate triggering of electrical stimulation delivery when the phone is in close proximity (within 25 cm) to the IPG and the lead.

Advise patients to hold the phone to the ear opposite the side of the implanted IPG. Patients should not carry the phone in a breast pocket or on a belt over or within 25 cm of the implanted IPG because some phones emit signals when they are turned on though not in use.

Airport Screening Systems

Globally, passenger-screening systems encountered in airports may interfere with the IPG. Most commonly, interference may result in electrical stimulation inhibition. Instruct patients to inform security personnel about the implanted medical device, to show their identification card, and to walk at a normal pace when passing through the portal of these systems. No damage to the implanted system should occur.

Magnets

Application of a magnet directly over the IPG for at least 2 consecutive seconds, followed by 2 consecutive seconds without a magnet, will terminate therapy for 24 hours.

General Precaution

The EndoStim System may fail to properly operate for any number of reasons, including but not limited to: random component failure (including the battery), lead failure (including electrical shorts, opens, and insulation faults), and software errors. The frequency of these events cannot be predicted.

System Overview

This section provides descriptions of all the components for the EndoStim® Lower Esophageal Sphincter Stimulation System. Throughout the instructions in this manual, you may see the terms stimulator and IPG (implantable pulse generator). These terms refer to the same type of device.

The system consists of an IPG, bipolar stimulating lead, and a Programmer.

Figure 1 EndoStim LES System

Implantable Pulse Generator

General Description

The EndoStim II implantable pulse generator (IPG) (Figure 2), is an internally powered (lithium battery) device that delivers electrical stimulation pulses to the lower esophageal sphincter (LES). The IPG is hermetically sealed in a titanium case. It delivers electrical pulses to the LES via a bipolar IS-1 BI header connector port (Figure 3) that connects the IPG and lead. The IPG is sterilized with ethylene oxide.

Figure 2 EndoStim II LES Stimulator

Figure 3 IPG Header Connector

The programmable IPG communicates with the external Programmer via telemetry. Medical and technical personnel use the Programmer to program parameters that control the IPG function. The IPG may be programmed specifically for individual patients by changing the settings parameters within the implanted device. In addition, the Programmer can access performance data that the IPG collects during its normal operation.

Handling and Storage

Do not implant the IPG if the package is damaged or if the IPG has been dropped from a height of 30 cm or more. Return damaged packages to EndoStim B.V.

Store the IPG at a temperature range of 20°C to 25°C and in a dry location. Do not allow the sterile packaging to become damp or wet because sterilization of the contents may be compromised. Exposure to temperatures below 0°C may cause a change in the parameter values of the IPG to the DOWN mode (no output). Once the IPG is removed from the extreme environment, it will either return to the programmed settings, or it will remain in the DOWN mode. In the latter case, follow the Reset procedure. If unsuccessful, the unit should be returned to EndoStim B.V.

Re-sterilization and Re-Use

The IPG and torque wrench are single-use devices. Do not re-sterilize the IPG or torque wrench. Do not re-use an explanted IPG: the device must not be used for implantation in another patient.

X-Ray Identification

A radiopaque marker placed within the IPG allows the model number and year of manufacture to be identified by normal X-ray techniques. The manufacturer's identification code for EndoStim is E, the code for the EndoStim II IPG model is B, and the code for the year of manufacture is XX, where XX is replaced by the last two digits of the calendar year in which the device was manufactured.

Implantable Bipolar Stimulating Lead

General Description

The EndoStim lead, called the Implantable Bipolar Stimulating Lead, is used in conjunction with the IPG. The lead has an IS-1-BI connector[1] at the proximal end for attachment to the IPG (Figure 4). The lead is sterilized with ethylene oxide.

The lead delivers stimulation pulses to the tissue through stitch electrodes at the distal end. During implantation, the stitch electrodes of the leads are sutured into the LES and secured into place. The electrodes of the bipolar lead are implanted in the sero-muscular layer of the LES (Figure 5).

Figure 4 EndoStim Lead and IPG

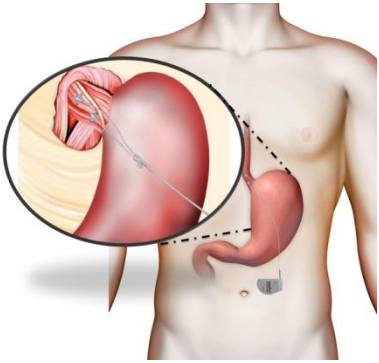

Figure 5 Implanted EndoStim Lead and IPG

[1] Implants for Surgery – Cardiac Pacemakers – Part 3: Low-profile connectors [IS-1] for implantable pacemakers, ISO 5841-3:2000(E)

Physical Characteristics

The implantable lead is constructed of biocompatible materials: an inner and outer silicone rubber sheathing, cobalt/nickel conductors, and platinum-iridium stitch electrodes. A curved stainless steel suture needle is affixed to the end of each stitch electrode. The lead is 45 cm in length from the IS-1-BI connector tip to the end of the platinum-iridium electrodes. The lead bifurcates after 35 cm into individual, unipolar leads, with the length of each unipolar lead being 10 cm.

Handling and Storage

Do not implant the lead if the package is damaged or if the lead has been dropped from a height of 30 cm or more. Return damaged packages to EndoStim, B.V.

Store the lead at a temperature range of 20°C to 25°C and in a dry location. Do not allow the packaging to become damp or wet because sterilization of the contents may be compromised.

Re-Sterilization and Re-Use

The lead is a single-use device. Do not re-sterilize the lead or silicone stoppers. Do not re-use an explanted lead; the device must not be used for implantation in another patient.

Programmer

General Description

Use the EndoStim LES System Programmer to interrogate and program the IPG. The Programmer software runs on an IEC60950 certified tablet personal computer (PC), which runs on battery power. Communication between the Programmer and the IPG is accomplished with the Programmer placed directly over the implant site. The Programmer communicates via magnetic induction telemetry with the IPG implanted in the patient.

Note: Avoid skin contact between the patient's skin and the Programmer Wand, when possible, to avoid any potential cross-contamination from previous use of the Programmer.

The Programmer can

- Read (interrogate) IPG parameters as currently programmed
- Modify IPG parameters
- Retrieve statistics accumulated by the IPG as it operates
- Log the activity of the IPG
- Store standard programs for future use

The Programmer has 2 components (Figure 6):

- Programmer Wand
- Programmer Tablet PC with Software

Figure 6 EndoStim LES System Programmer

Electrical Characteristics

The Programmer is internally-powered Type B equipment that is suitable for continuous use.

The Programmer is considered an applied part and the Programmer tablet PC is considered out of the patient environment (at least 1.5 meters from the patient).

The Programmer can communicate to the IPG at a maximum distance of 5.0 cm.

Maintenance

The Programmer Wand does not contain any user serviceable parts. If any Programmer Wand parts become damaged or loose, or it does not function properly, return the Programmer Wand to EndoStim B.V.

After each use, it is recommended that you disconnect the Programmer Wand from the USB port of the tablet PC. To clean the Programmer, use a soft cloth dampened with distilled water, methanol, or isopropyl alcohol to wipe the exterior case of the Programmer Wand. Do not use solvents or cleaning cloths infused with chemical cleaning agents.

Warnings:

- The Programmer is not protected against the ingress of water (IXP0). Avoid immersing the Programmer in any fluids.
- Do not use the Programmer in the presence of flammable anesthetics.
- Do not sterilize the Programmer.
- Do not connect any other equipment to the Programmer.
- Do not modify the Programmer in any way.

Handling and Storage

Do not use the Programmer if the package is damaged or if the Programmer has been dropped from a height of 1 meter or more. Return damaged packages to EndoStim B.V.

The Programmer environmental conditions are found in Table 1.

Table 1 Environmental Conditions for the Programmer

Condition	Shipping	Operating and Storage
Temperature	-20-70 ºC (-4-158 ºF)	5-37 ºC (41-104 ºF)
Humidity	15-93 % non-condensing	15-93 % non-condensing
Atmospheric Pressure	54.0-101.3 kPa (7.8-14.7 psi)	54.0-101.3 kPa (7.8-14.7 psi)
Altitude	0-5000 m (0-16,404 ft)	0-5000 m (0-16,404 ft)

Environmental conditions for the tablet PC may be different than the Programmer. Check tablet PC user manual for tablet PC environmental ranges and assume worst case condition.

Service Life and Disposal

The life of service is expected to be 5 years. The Programmer should be returned to EndoStim B.V. when disposal is required.

Environment of Use and Operator Profile

The operators of the Programmer include physicians in charge of either implanting or monitoring an IPG, and trained medical personnel who assist physicians. Operators will be familiar with operation of electronic medical equipment, particularly IPGs, and programmers and / or the operators will have been trained on the operation of the EndoStim Programmer.

The Programmer is used in an operating room where the IPG is being implanted. When in the operating room, the Programmer should be brought into the sterile field through a sterile sleeve while the tablet PC remains outside the sterile field. The surgeon should place the Programmer over the IPG while an appropriate person outside the sterile field operates the Programmer.

The Programmer is also used in a clinical room where patients with an implanted IPG are monitored. When in the clinic, the clinician should place the Programmer over the IPG and have either an assistant or the patient hold the Programmer in place. The patient can sit or lie down. The tablet PC should be outside the patient environment, at least 1.5 meters away, and operated by the clinician.

To be compliant with electromagnetic compatibility requirements (interference characteristics), the Programmer should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, verify that the Programmer functions properly. It is recommended to have an additional Programmer present at each implant and clinic visit.

Implant the EndoStim System

Laparoscopic surgery is generally used for the implantation of the EndoStim System. An open, bariatric surgical approach may also be appropriate for some patients. Minimal use of narcotics is recommended. Follow standard sterile technique and adhere to standard operating room procedures.

Warning: The implanting physician is required to undergo formal training by an EndoStim expert representative prior to implanting the system in humans.

MRI Information for the EndoStim System

It is important to read the section in its entirety before conducting any magnetic resonance imaging (MRI) examination on a patient implanted with the EndoStim System.

Contact an EndoStim representative with any questions regarding the following MRI information.

If all the instructions below are followed, MRI examinations of the regions using a transmit/receive RF local coil (e.g., head coil) *only* may be safely performed at 1.5-Tesla/64-MHz or 3-Tesla/128-MHz. Failure to carefully follow the specific information presented in this document may result in serious patient injury and/or damage to the EndoStim System.

Potential Interactions with the EndoStim System

MRI-Related Heating

The MRI uses radiofrequency (RF) energy which may cause excessive heating of the pulse generator and lead of the EndoStim System during the MRI examination.

Notes:

High specific absorption rate (SAR) RF power levels can increase the risk of heating.

Excessive heating of the lead may occur even if the IPG is explanted.

Magnetic Field Interactions

MRI uses a powerful static magnetic field which may exert force and torque on the metallic objects that could result in movement or displacement. Tests performed at 1.5-Tesla and 3-Tesla indicated that this is not a concern for the EndoStim System.

Warnings and Precautions

EndoStim Programmer System

The EndoStim Programmer contains ferromagnetic materials. These materials could make the Programmer susceptible to the powerful static magnetic field of the MR system. Therefore, the EndoStim Programmer System is considered MR Unsafe, meaning that it cannot be present and/or used in the same room as the MR system. The pre- and post-exposure implanted pulse generator programming requirements (detailed below) must be performed *outside* of the MR system room.

Other Implanted Systems

Prior to MRI examination, the patient should be evaluated for other implanted medical devices, especially electronically-activated devices. An x-ray may be used to determine if the patient has other implanted medical devices.

The decision to perform an MRI examination must be made by the MRI-trained radiologist, and the patient's physician, in consideration of the risks and benefits to the patient.

MR System Type

1.5-Tesla/64-MHz and 3-Tesla/128-MHz MR systems are the only types of equipment permitted for use for a patient with the EndoStim System. There is no restriction on the MRI manufacturer.

Other MR systems (e.g., 0.6-Tesla, etc.) are not permitted for use and may cause serious patient injury and/or damage to the EndoStim System.

MR System RF Coil – Use of Transmit/Receive RF Local Coil, ONLY

A transmit/receive RF local coil is the only type of RF coil permitted for use in a patient with the EndoStim System.

The transmit/receive RF body coil must not be used.

No portion of the RF transmit/receive local coil can cover any part of the implantable system. The diagram below illustrates the region that is considered unsafe for MRI exposure,

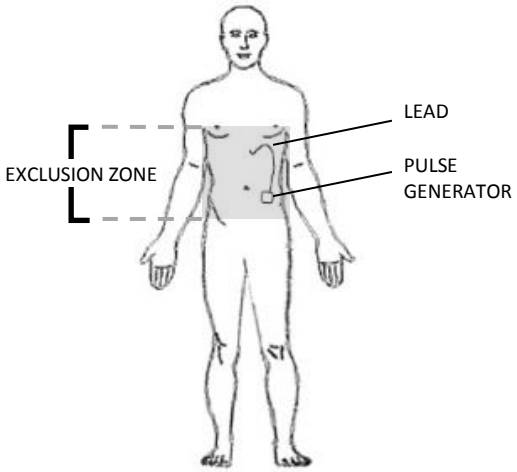

Figure 7 Unsafe MR Imaging Region (highlighted in grey)

This exclusion zone is dependent on the typical placement of the EndoStim II IPG and Lead. Implanted system components may be located as close as 0cm to the lower (caudad) edge of the transmit/receive RF local coil, but no part may be inside of it.

Brain/head imaging should be performed using a transmit/receive RF head coil *only*. The diagram below illustrates the required placement of the transmit/receive RF head coil, as shown in grey. Under no circumstances is the transmit/receive RF head coil allowed to overlap with the off-limits area as shown in Figure 7.

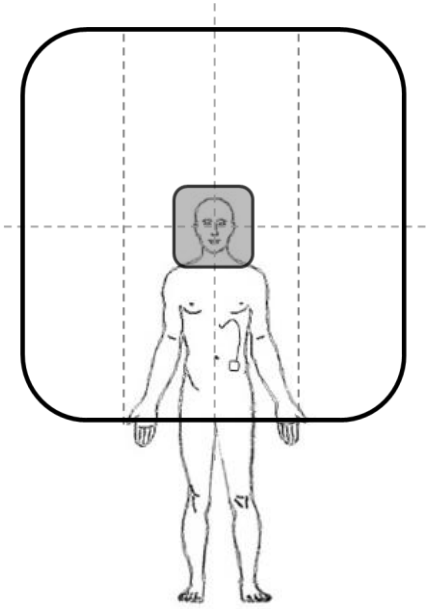

Figure 8 Brain MR Imaging Region with Head RF Coil

Extremity imaging should be performed using an appropriate transmit/receive RF local coil *only*. The diagrams below illustrate several examples of the required placement of the transmit/receive RF local coil, as shown in grey. Under no circumstances is the transmit/receive RF head coil allowed to overlap with the off-limits area as shown in Figure 7.

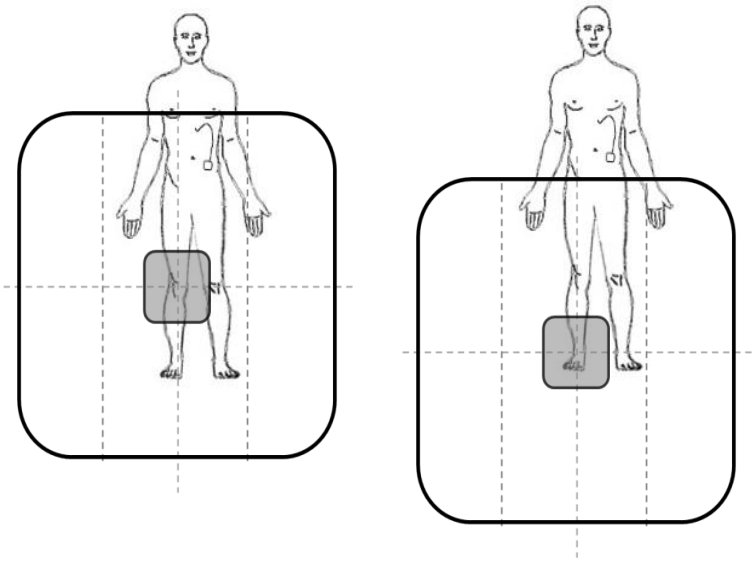

Figure 9 MR Imaging Region Knee and Ankle with Local RF Coil

If these instructions are not followed, higher than normal heating may occur at the lead electrodes. If the patient has a broken lead, higher than normal heating can also occur at the break if in the area of the transmission of the RF energy. Excessive heating can cause tissue damage or serious patient injury.

Consult the MR system manufacturer for questions regarding the type of RF coil in use with the 1.5-Tesla/64-MHz or 3-Tesla/128-MHz MR system.

MRI Parameters

The RF frequency must be 64-MHz or 128-MHz, ONLY. Other frequencies have not been tested. These could lead to tissue damage or serious patient injury. Furthermore, use of other transmit frequencies could cause device damage and/or excessive heating.

The RF power should be limited to a specific absorption rate of 1-W/kg or less, in the head and whole body, for each pulse sequence.

The spatial gradient should be limited to 250 Gauss/cm or less.

The isocenter location landmark should be the region of interest ONLY.

Preparing the Patient prior to MRI Procedure

The patient should be informed to bring the Patient ID card to the MRI procedure appointment and to inform the MR system operator that he/she has an active implantable medical device prior to entering the MR system room.

The patient should be informed that the therapy will be turned off until after the MRI procedure is completed.

The IPG should be programmed to OFF (reference section Program Stimulation Amplitude and Polarity).

Important Note: If the IPG is in End of Life (reference section IPG Battery Characteristics and Specifications), then the IPG mode cannot be programmed or confirmed via telemetry and the MRI procedure cannot be performed.

The patient should be informed of all risks associated with undergoing an MRI procedure with a transmit/receive RF local coil *only* (reference the Warning and Precautions section in this chapter).

The patient should be informed to immediately inform the MR system operator of any discomfort, stimulation, shocking, or unusual sensation that may occur during the MRI procedure.

The patient should be conscious throughout the MRI examination (i.e., no sedation or anesthesia is allowed).

Beginning of the MRI Procedure

Verify the patient's weight is entered correctly into the MR system's console to ensure that the regional SAR is correctly calculated.

Verify that the MR system's transmit/receive RF local coil is being used.

Verify that the MR system transmit/receive RF body coil is not being used.

Verify the MRI parameters for compliance with the requirements in this section. If the parameters are not compliant, they should be adjusted to meet the requirements. If this is not possible, the MRI procedure must not be performed.

Verify that the Programmer is not in the same room as the MR system.

During the MRI Procedure

The EndoStim System should not activate (turn on) or conduct any energies into a stimulation.

There should be no visual artifacts from the EndoStim System as it is not to be placed within the transmit/receive RF local coil.

Monitor the patient visually and audibly during, and between, the MR imaging sequences to ensure the patient is not having any difficulty.

During the MRI procedure, the patient may feel vibration of the IPG.

Discontinue the MRI procedure immediately if the patient reports any issues, is unable to respond to any questions, or the IPG movement or vibration is too uncomfortable.

Do not, under any circumstances, attempt to program the IPG while the patient is in the same room as the MR system.

After the MRI Procedure

Verify that the patient has not experienced any adverse effects during the MRI procedure.

Once outside of the MR system room, reset the IPG using the Programmer. Reprogram the parameter values to those prior to the MRI procedure and enable stimulation. Any problem with these programming steps indicates that the IPG may have been damaged due to the MRI examination.

Immediately report any device-related issues to the implanting physician and EndoStim.

System Specifications

This section contains specifications and characteristics for all the devices included in the LES system: IPG, Bipolar lead, and Programmer.

IPG Specifications

Table 2 Implantable Pulse Generator Specifications

Description	Value
Height	62 mm
Width	39 mm
Thickness	8.4 mm
Mass	28.5 g
Biocompatible materials in contact with human tissue	Titanium Epoxy resin Silicone rubber set plugs
Power source	Lithium carbon monoflouride battery
Storage temperature	20°C to 25°C

IPG Battery Characteristics and Specifications

The battery voltage at beginning of life is approximately 3.3V and the usable capacity is 2.5 Ah. When battery voltage falls below 2.5V, the device sends information to the Programmer, upon interrogation, that the battery is near the end of life. In addition, stimulation amplitude will be reduced if programmed at greater than 3 times the battery voltage. When battery voltage falls below 2.3V, the device will turn off all stimulation outputs. When the battery voltage falls below 2.1V, communication with the Programmer will no longer be possible.

The longevity of the battery can be estimated based on the different stimulating parameters applied, as described in Table 3.

Table 3 Estimated IPG Battery Longevity

Parameter	Condition 1	Condition 2	Condition 3	Condition 4
Pulse Width[a]	215 μsec	215 μsec	215 μsec	215 μsec
Pulse Frequency[a]	20 Hz	20 Hz	20 Hz	20Hz
Pulse Amplitude	5.0 mA	5.0 mA	3.5 mA	7.5 mA
Hours per Day	3.0	6.0	4.0	4.0
Estimated Life[b]	8.6 years	6.6 years	7.8 years	5.8 years

[a] This is the recommended value
[b] This assumes a 12 month shelf life prior to implant

Lead Characteristics and Specifications

Table 4 Lead Physical Description and Materials

Lead	Specification
Connector	IS-1 BI
Length	45 cm
Mass	4 g
Electrodes	Platinum-iridium
Bifurcation	At 35 cm, lead has two 10cm unipolar segments

Programmer Specifications

Table 5 Programmer Specifications

Description	Value
Height	140 mm
Width	62.7 mm
Thickness	30.5 mm
Mass	251 g
Storage temperature	5°C to 37°C

Safety Shutdown with a Magnet

Therapy signal delivery of the IPG can be shut down for 24 hours if it is exposed to a magnetic field. A standard pacemaker safety magnet can be used.

Electromagnetic Interference

The center frequency of the EndoStim Programmer transmitter (to the EndoStim II IPG) is 20 kHz with a bandwidth of 18 kHz to 22 kHz.

The center frequency of the EndoStim Programmer receiver (from the EndoStim II IPG) is 10 kHz to 28 kHz.

Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emissions

The EndoStim II IPG and Programmer are intended for use in the electromagnetic environment specified in Table 6. The customer or user of the EndoStim II IPG and Programmer should assure that it is used in such an environment.

Table 6 Electromagnetic Emissions

The EndoStim II IPG and Programmer are intended for use in the electromagnetic environment specified below. The customer or user of EndoStim II IPG and Programmer should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The EndoStim II IPG and Programmer use RF energy only for its internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The EndoStim II IPG and Programmer are suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage supply network that supply buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Not Applicable	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-2		

ESD and Power Fluctuations

Guidance and manufacturer's declaration – electromagnetic immunity

The EndoStim Programmer is intended for use in the electromagnetic environment specified in Table 7. The customer or user of the EndoStim Programmer should assure that it is used in such an environment.

Table 7 ESD and Power Fluctuations: Electromagnetic Immunity

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	Not Applicable	Not Applicable	Mains power should only be used to recharge the tablet PC battery while the unit is powered off.
Surge IEC 61000-4-5	Not Applicable	Not Applicable	Mains power should only be used to recharge the tablet PC battery while the unit is powered off.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not Applicable	Not Applicable	Mains power should only be used to recharge the tablet PC battery while the unit is powered off.
Power frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a residential environment.

Radiated Electromagnetic Fields

Guidance and manufacturer's declaration – electromagnetic immunity

The EndoStim Programmer is intended for use in the radiated electromagnetic fields specified in Table 8. The customer or user of the EndoStim Programmer should assure that it is used in such an environment.

Portable and mobile RF communications equipment should be used no closer to any part of the EndoStim Programmer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Table 8 Radiated Electromagnetic Fields: Electromagnetic Immunity

Immunity test	IEC 60601Test level	Compliance level	Recommended Separation Distance
Conducted RF, IEC 61000-4-6, 150 kHz to 80 MHz outside ISM bands	3 Vrms	3 Vrms	$d = 1.17\sqrt{P}$
Conducted RF, IEC 61000-4-6, 150 kHz to 80 MHz inside ISM bands	3 Vrms	3 Vrms	$d = 1.20\sqrt{P}$
Radiated RF, IEC 61000-4-3, 80 MHz to 800 MHz	3 V/m	3 V/m	$d = 1.20\sqrt{P}$
Radiated RF, IEC 61000-4-3, 800 MHz to 2.5 GHz	3 V/m	3 V/m	$d = 2.30\sqrt{P}$

Notes:

- P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, and d is the recommended separation distance in meters (m).
- Field strengths from fixed radio frequency (RF) transmitter, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b]
- Interference may occur in the vicinity of equipment marked with the ionizing radiation symbol:

At 80 MHz and 800 MHz, the higher frequency range applies.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a]Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the EndoStim Programmer is used exceeds the applicable RF compliance level above, the EndoStim Programmer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as relocating the EndoStim Programmer.

[b]Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the EndoStim Programmer

The EndoStim Programmer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled (**Table 9**). The customer or user of the EndoStim Programmer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the EndoStim Programmer as recommended (according to the maximum output power of the communications equipment).

Table 9 Recommended Separation Distances Between RF Equipment and EndoStim Programmer

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz $d = 117\sqrt{P}$	80 MHz to 800 MHz $d = 0.35\sqrt{P}$	800 MHz to 2.5 GHz $d = 0.70\sqrt{P}$
0.01	0.12	0.04	0.07
0.1	0.37	0.11	0.22
1	1.17	0.35	0.7
10	3.7	1.11	2.22
100	11.7	3.5	7.0

Notes:

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated by using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

- At 80 MHz and 800 MHz, the higher frequency range applies.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Range and Tolerance of Displayed Values

IPG and Lead Parameters			
Parameter	**Range**	**Increment**	**Tolerance**
Serial	0001 to 9999	1	N/A
Battery	2.10 to 3.10 (V)	0.01V	0.05V
Impedance	200 to 2000 (Ω)	1 Ω	Max of 100Ω and 20%
Stimulation Parameters			
Parameter	**Range**	**Increment**	**Tolerance**
Pulse Width	30 to 975 (μsec)	30μsec	Max of 5% and 15μsec
Pulse Amplitude	2.0 to 10.0 (mA)	0.5mA	Max of 0.5mA and 20%
Pulse Rate	2 to 80 (Hz)	2-10Hz: 1Hz 10-40Hz: 2Hz 40-80Hz: 5Hz	Max of 1% and 100μsec
Active Time	00:00:01 to 23:59:59	1sec	2sec
Inactive Time	00:00:01 to 23:59:59	1sec	2sec
Duty Cycle	1 to 99 (%)	1%	1%
Dose Mode Parameters			
Parameter	**Range**	**Increment**	**Tolerance**
Dose Time	00:00:01 to 23:59:59	1sec	2 sec
Block Time	0.5 to 4.0 (hr)	0.5hr	2 sec
Dose Schedule	00:00 to 23:30	30min	2 min
Sensing Parameters			
Parameter	**Range**	**Increment**	**Tolerance**
Supine Time	1, 5, 30, or 60 (min)	N/A	1 min
Supine Level	50 to 80 (˚)	10˚	10˚
Minute %	70, 80, 90, or 95 (%)	N/A	1%

Supine Time %	70, 80, 90, or 95 (%)	N/A	1%

Service and Warranty

EndoStim provides emergency device consultation on a 24-hour basis. If you require emergency assistance, please contact the following number +1-866-510-1003.

EndoStim warrants that all IPGs and accessories (including associated firmware and software) will be free from defects in workmanship and materials for a period of 12 months after the original implantation of the IPG (the "Warranty Period").

If it appears that an IPG contains a defect in workmanship or materials, or fails to conform to applicable specifications, EndoStim will replace the defective or non-conforming components free of charge. The Warranty Period for a replaced component shall be the longer of the time remaining on the original Warranty Period or nine months from delivery of the replaced item.

If a system component completely fails to function within the first 72 hours of operation, EndoStim will replace the failed item with a new one.

EndoStim shall not be liable under this warranty if testing and examination discloses that the alleged defect or non-conformity in the system component does not exist or was caused by the end user's misuse, neglect, improper implantation or testing, unauthorized attempts to repair, or by accident, fire, lightning or other hazard.

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